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Attorneys for Defendant

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

PFIZER INC., PHARMACIA & UPJOHN COMPANY LLC, and PFIZER HEALTH AB Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC. Defendant.	CIVIL ACTION No: 07-11198-LTS

ANSWER AND COUNTERCLAIMS
OF TEVA PHARMACEUTICALS USA, INC.

Defendant Teva Pharmaceuticals USA, Inc. ("Teva") hereby responds to the Complaint of Pfizer Inc., Pharmacia & Upjohn Company LLC, and Pfizer Health AB (collectively, "Pfizer") as follows:

THE PARTIES

1. Teva is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 1.

2. Teva is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 2.

3. Teva is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 3.

4. Teva admits that it is a corporation organized and existing under the laws of the State of Delaware, and having a place of business at 1090 Horsham Road, North Wales Pennsylvania.

JURISDICTION AND VENUE

5. The allegations in paragraph 5 state a conclusion of law to which no response is required.

6. The allegations in paragraph 6 state a conclusion of law to which no response is required.

7. The allegations in paragraph 7 state a conclusion of law to which no response is required. .

U.S. Patent No. 5,382,600

8. Teva admits that United States Patent No. 5,382,600 (the "'600 Patent") is entitled "3,3-Diphenylpropylamines and Pharmaceutical Compositions Thereof" and that it was issued by the United States Patent and Trademark Office on January 17, 1995. Teva admits that Pharmacia Aktiebolag is listed as the assignee on the face of the '600 Patent. Teva admits that what appears to be a true and correct copy of the '600 Patent is attached as Exhibit A to the Complaint. Teva is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations in paragraph 8.

9. The allegations in paragraph 9 state a conclusion of law to which no response is required. Further answering, Teva states that the '600 Patent speaks for itself.

U.S. Patent No. 6,630,162

10. Teva admits that United States Patent No. 6,630,162 (the "'162 Patent") is entitled "Pharmaceutical Formulation and its Use" and that it was issued by the United States Patent and Trademark Office on October 7, 2003. Teva admits that Pharmacia AB is listed as the assignee on the face of the '162 Patent. Teva admits that what appears to be a true and correct copy of the '162 Patent is attached as Exhibit B to the Complaint. Teva is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations in paragraph 10.

11. The allegations in paragraph 11 state a conclusion of law to which no response is required. Further answering, Teva states that the '162 Patent speaks for itself.

U.S. Patent No. 6,770,295

12. Teva admits that United States Patent No. 6,770,295 (the "'295 Patent") is entitled "Therapeutic Formulation for Administering Tolterodine with Controlled Release" and that it was issued by the United States Patent and Trademark Office on August 3, 2004. Teva admits that Pharmacia AB is listed as the assignee on the face of the '295 Patent. Teva admits that what appears to be a true and correct copy of the '295 Patent is attached as Exhibit C to the Complaint. Teva is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations in paragraph 12.

13. The allegations in paragraph 13 state a conclusion of law to which no response is required. Further answering, Teva states that the '295 Patent speaks for itself.

Detrol LA®

14. Teva admits that the electronic version of the Food and Drug Administration ("FDA") publication entitled "Approved Drug Products with Therapeutic Equivalence

Evaluations" ("Orange Book") identifies Pharmacia & Upjohn Company LLC as the holder of an approved New Drug Application for tolterodine tartrate extended release capsules, in 2 and 4 mg dosages. Teva further admits that the Orange Book identifies the proprietary name of tolterodine tartrate extended release capsules, in 2 and 4 mg dosages, as Detrol LA®. Teva is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations in paragraph 14.

15. Teva admits that the '600, '162 and '295 Patents are listed in the Orange Book with respect to the Detrol LA® drug product.

Teva's ANDA

16. Teva admits that it submitted Abbreviated New Drug Application ("ANDA") No. 79-141 seeking FDA approval to engage in the commercial manufacture, use, or sale of tolterodine tartrate extended release capsules, in 2 and 4 mg dosages ("Teva's Tolterodine ER Product").

17. Teva admits that its ANDA No. 79-141 refers to the Detrol LA NDA and contains data that Teva believes demonstrates the bioequivalence of Teva's Tolterodine ER product and Detrol LA®. Teva denies the remaining allegation in paragraph 17.

18. Teva admits that it sent to Pfizer Inc. and others a "Patent Certification Notice" ("Notice Letter") on October 29, 2007, stating that Teva had submitted ANDA No. 79-141, seeking approval of Teva's Tolterodine ER Product. Teva admits that the Notice Letter states that ANDA No. 79-141 contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certifications") that the claims of the '600, '162 and '295 Patents are invalid, unenforceable or will not be infringed by the commercial manufacture, use, or sale of Teva's Tolterodine ER Product. Teva denies the remaining allegations in paragraph 18.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 5,382,600

19. Each of preceding paragraphs 1 through 18 is incorporated as if fully set forth herein.

20. Teva denies the allegations in paragraph 20.

21. Teva denies the allegations in paragraph 21.

22. Teva denies the allegations in paragraph 22.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 6,630,162

23. Each of preceding paragraphs 1 through 18 is incorporated as if fully set forth herein.

24. Teva denies the allegations in paragraph 24.

25. Teva denies the allegations in paragraph 25.

26. Teva denies the allegations in paragraph 26.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 6,770,295

27. Each of preceding paragraphs 1 through 18 is incorporated as if fully set forth herein.

28. Teva denies the allegations in paragraph 28.

29. Teva denies the allegations in paragraph 29.

30. Teva denies the allegations in paragraph 30.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

Invalidity of the '600, '162 and '295 Patents.

31. All of the claims of the '600, '162 and '295 Patents are invalid under 35 U.S.C. § 101 *et seq*.

SECOND AFFIRMATIVE DEFENSE

Non-Infringement of the '162 and '295 Patents.

32. The manufacture, use, offer for sale, sale or importation of Teva's Tolterodine ER Product does not and will not infringe any valid and enforceable claim of the '162 and '295 Patents.

THIRD AFFIRMATIVE DEFENSE

Unenforceability of the '600 Patent for Inequitable Conduct Before the Patent and Trademark Office.

Introduction

33. This matter concerns, *inter alia,* United States Patent No. 5,382,600 (the "'600 Patent") entitled "3,3-Diphenylpropylamines and Pharmaceutical Compositions Thereof" issued by the United States Patent and Trademark Office ("PTO") on January 17, 1995.

34. The named inventors, their attorneys and others who had substantive involvement in the prosecution of the '600 Patent owed a duty of candor and disclosure to the PTO under 37 C.F.R. § 1.56 with respect to and during the pendency of the prosecution of the '600 Patent. Individuals who had such a duty of candor and disclosure include inventors Nils A. Jönsson, Bengt A. Sparf, Lembit Mikiver, Pinchas Moses, Lisbeth Nilvebrant, and Gunilla Glas; originating/introducing Swedish patent agents or attorneys Per Arne Kummelsten and Bjorn Widen; and certain others, including Rolf Johansson and Per-Olof Andersson (hereinafter, collectively, "Applicants").

35. Applicants' duties included an obligation to disclose information material to the prosecution and patentability of the '600 Patent to the PTO, as required by the Manual of Patent Examiner Procedure ("M.P.E.P.") in effect during prosecution of the '600 Patent, which stated the following:

> Applicants and other individuals, as set forth in 37 C.F.R. 1.56, have a duty to bring to the attention of the Office any material prior art or other information cited or brought to their attention in any related foreign application. The inference that such prior art or other information is material is especially strong where it is the only prior art cited or where it has been used in rejecting the same or similar claims in the foreign application.

M.P.E.P. § 2001.06(a).

36. The '600 Patent is unenforceable because Applicants breached their duty of candor and disclosure by intentionally failing to disclose German Patent No. 1216318 (the "Undisclosed German '318 Patent") and Swedish Patent No. 300 822 (the "Undisclosed Swedish '822 Patent") to the PTO during the prosecution of the '600 Patent despite their knowledge of these references and their high degree of materiality. Applicants failed to disclose these material references with the intent to deceive the PTO, and the '600 Patent is therefore rendered unenforceable by inequitable conduct.

37. The '600 Patent is also unenforceable because Applicants breached their duty of candor and disclosure by intentionally making material misrepresentations and misleading statements to the PTO in order to procure a patent. Applicants made these material misrepresentations and misleading statements with the intent to deceive the PTO, and the '600 Patent is therefore rendered unenforceable by inequitable conduct.

Background - Prosecution of the '600 Patent and Related Applications

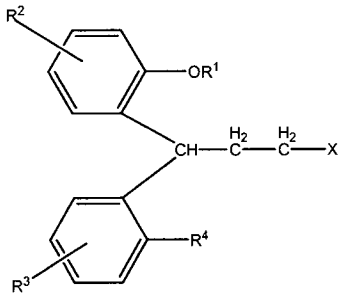
38. The '600 Patent issued from U.S. Patent Application Ser. No. 810,185 (the "'185 Application") entitled "3,3-Diphenylpropylamines and Pharmaceutical Compositions Thereof." The '185 Application was filed on December 19, 1991. At the time of filing, Kabi Vitrum AB, Stockholm, Sweden, was the designated assignee. The assignment was later changed to Pharmacia Aktiebiolag, Uppsala, Sweden, as appears on the face of the '600 Patent.

39. The '185 Application derived priority from an International Patent Cooperation Treaty ("PCT") Application No. 8900016 (the "'016 Priority Application"). The International Publication Number for the '016 Priority Application is WO8906644.

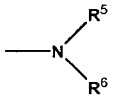
40. The '016 Priority Application was prosecuted by Kummelsten, Per Arne *et. al.*, attorneys from the Swedish law firm, Uppsala Patentbyra. Bjorn Widen was an attorney at Uppsala Patentbyra, who was specifically named as a prosecuting attorney on national applications which resulted from the '016 Priority Application. Upon information and belief, Bjorn Widen participated in the prosecution of the '016 Priority Application.

41. The '185 Application and the issued '600 Patent each identify Nils A. Jonsson, Bengt A. Sparf, Lembit Mikiver, Pinchas Moses, Lisbeth Nilvebrant and Gunilla Glas as inventors.

42. The '185 Application described and claimed diphenylpropylamines of formula I:



wherein R^1 signifies hydrogen or methyl, R^2, R^3 and R^4 independently signify hydrogen, methyl, methoxy, hydroxy, carbamoyl, sulphamoyl or halogen, and X represents a tertiary amino group of formula II



wherein each of R^5 and R^6 independently signifies C_{1-6} alkyl, which may be joined to form a ring with the amine nitrogen and each of which may carry a hydroxy substituent, or adamantyl, and wherein R^5 and R^6 together contain at least three carbon atoms, preferably at least 4 carbon atoms, their salts with

physiologically acceptable acids and, when the compounds can be in the form of optical isomers, the racemic mixture and the individual enantiomers.

A. Failure To Disclose Certain Prior Art

1. *Failure to Disclose German Patent No. 1216318*

43. During prosecution of the '185 Application, the examiner rejected claims 1 to 4, 6 and 9 to 15 "under 35 U.S.C. § 103 as obvious over the German, British and U.S. patents and the Chemical Abstracts article cited in the corresponding PCT application [the '016 Priority Application]." The '016 Priority Application cited two British patents (GB 1169944 and GB 1169945), one U.S. patent (3,446,901), and Chemical Abstract, Vol. 97 (1982) 120105N. It did not cite any German patents. The examiner requested copies of "the German [and] British … patents" from the Applicants for his review.

44. When the examiner made the request and otherwise during the prosecution of the '600 Patent, Applicants were aware of a highly material German patent, German Patent No. 1216318 ("Undisclosed German '318 Patent"). Applicants' knowledge is evidenced by the fact that the face of the Danish Patent No. 111894 ("Danish '894 Patent"), which was provided to the examiner by Applicants, cites to the application for the Undisclosed German '318 Patent for priority, a fact which was highlighted by the examiner of the '185 Application's request for a German reference.

45. Applicants' knowledge of the Undisclosed German '318 Patent is further evidenced by the fact that, in a related application, the Undisclosed German patent was identified to several of Applicants as "document of particular relevance," and was cited as invalidating prior art.

46. During the prosecution of the '185 Application, Swedish Application No. 92003318 (the "Swedish Metabolite Application") was filed on November 6, 1992. The

specification and claims of the Swedish Metabolite Application were submitted as a PCT application, No. SE93/00927, on November 5, 1993 (the "PCT Metabolite Application").

47. The specification of the PCT Metabolite application specifically references the subject matter of the '185 Application, and the compounds claimed in the PCT Metabolite Application only differ from those claimed in the '185 Application (as described in Formula I, paragraph 29 above) by one substituent group – the R^2 group in the PCT Metabolite Application is specified as a methanol group.

48. Three of the inventors identified in the '185 Application and the '600 Patent, Bengt A. Sparf, Pinchas Moses, and Lisbeth Nilvebrant, are also identified as inventors on the PCT Metabolite Application. In addition, the PCT Metabolite Application was prosecuted by Bjorn Widen, an attorney at Uppsala Patentbyra. Thus, inventors Bengt A. Sparf, Pinchas Moses and Lisbeth Nilvebrant, and attorney Bjorn Widen participated in the prosecution of both the PCT Metabolite Application and the '185 Application (which issued as the '600 Patent).

49. The examiner of the PCT Metabolite Application designated the Undisclosed German '318 Patent as type "X" in an International Search Report ("ISR") sent to inventors Sparf, Moses and Nilvebrant and attorney Widen on February 7, 1994. A type "X" reference is defined in the ISR as a "document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when taken alone."

50. The examiner of the PCT Metabolite Application also designated WO8906644 (the formal publication of the '016 Priority Application, which is the predecessor of the '185 Application) as a type "X" reference. The examiner determined that the predecessor of the '185 Application was invalidating prior art and on that basis refused the PCT Metabolite Application.

51. A reasonable PTO examiner would have considered the Undisclosed German '318 Patent to be highly material to the patentability of the '185 Application for at least the following reasons: (1) the Undisclosed German '318 Patent was designated as particularly relevant prior art regarding the PCT Metabolite Application, which specifically references the subject matter of the '185 application and, with the exception of one substituent group, claims compounds identical to those claimed in the '185 Application, (2) the teachings of Undisclosed German '318 Patent are inconsistent with and could not have been distinguished by arguments made by Applicants, and (3) the Undisclosed German '318 Patent discloses compounds that are claimed in the '185 Application and the '600 Patent, and therefore anticipates the claims of the '600 Patent and/or renders the claims of the '600 Patent obvious.

52. Applicants also had knowledge of the materiality of the Undisclosed German '318 Patent while prosecuting the '185 Application. Applicants' knowledge is evidenced by (1) the determination in the ISR that the Undisclosed German '318 Patent was of type "X", and therefore invalidated the claims of the Swedish Metabolite Application; (2) the fact that the Undisclosed German '318 Patent described a class of compounds that contained an alkoxy substituent, which description is inconsistent with and avoids Applicants' argument for distinguishing the claimed compounds of the '185 Application from the related Danish '894 Patent; and (3) the fact that the Undisclosed German '318 Patent described a class of compounds identical to a subset of the claims of the '185 Application and the '600 Patent, and therefore anticipated those claims.

53. Despite the PTO examiner's request for the German patent and despite their knowledge of such patent and its high degree of materiality, Applicants did not provide a copy nor did they disclose to the PTO the Undisclosed German Patent. Applicants intentionally failed

to disclose the Undisclosed German '318 Patent to the PTO because it would have invalidated claims in the '185 Application (which issued as the '600 Patent).

54. Instead, in their response to the examiner's request for the German patent, Applicants cited and produced to the examiner Danish Patent No. 111894 (the "Danish '894 Patent"). The Danish '894 Patent, on its face, claimed priority to German Patent Application No. K48245, filed in November, 1962, which application issued as the Undisclosed German '318 Patent.

55. In further response to the examiner's rejection, Applicants distinguished the Danish '894 Patent by arguing that it did not teach placing an hydroxy or alkoxy substituent in the ortho position of the phenyl rings. That argument would not have distinguished the Undisclosed German '318 Patent, however, which discloses an alkoxy substituent in the ortho position of the phenyl rings.

56. As a result, Applicants breached their duty of candor under 37 C.F.R. § 1.56 by intentionally failing to disclose the Undisclosed German '318 Patent to the examiner during the prosecution of the '185 Application with the intent to deceive the PTO and procure a patent. Applicants failed to disclose the Undisclosed German '318 despite their knowledge of the reference and its high degree of materiality. Therefore, the '600 Patent is rendered unenforceable by inequitable conduct.

2. *Failure to Disclose Material Swedish Patent No. 300 822*

57. Applicants also intentionally failed to disclose Swedish Patent No. 300 822 (the "Undisclosed Swedish '822 Patent") to the examiner during the prosecution of the '600 Patent despite their knowledge of this reference and its high degree of materiality. The Undisclosed Swedish '822 Patent, which claims priority to the Undisclosed German '318 Patent, is related to

and contains similar disclosures to the Danish '894 Patent. Like the Undisclosed German '318 Patent but unlike the Danish '894 Patent, the Undisclosed Swedish '822 Patent describes substituted diphenylpropylamines with an alkoxy substituent in the phenyl rings.

58. In response to the examiner's rejection for obviousness, Applicants distinguished the Danish '894 Patent by arguing that it did not teach placement of an hydroxy or alkoxy substituent in the ortho position of the phenyl rings. That argument would not have distinguished the Undisclosed Swedish '822 Patent, however, which discloses an alkoxy substituent in the ortho position of the phenyl rings.

59. A reasonable examiner would have considered the Undisclosed Swedish '822 Patent material to the patentability of the '185 Application because, in addition to the reasons stated as to the Undisclosed German '318 Patent in paragraphs 42 and 43 above, the Undisclosed Swedish '822 Patent describes compounds that fall within the claims of the '600 Patent, and thereby renders the claims of the '600 Patent anticipated and/or obvious.

60. Upon information and belief, Applicants were aware of the Undisclosed Swedish '822 Patent and its materiality during the prosecution of the '185 Application, as evidenced by the following: (1) Applicants disclosed the Danish '894 Patent, which is related to the Undisclosed Swedish '822 Patent and claims priority to the same parent; (2) the Undisclosed Swedish '822 Patent is issued by the Swedish Patent Office in the Swedish language and covers the class of compounds for which Applicants sought to obtain a patent; (3) Applicants are Swedish nationals, developed the compounds claimed in the '185 Application in Sweden, and filed a priority application to the '185 Application with the Swedish Patent Office; and (4) plaintiff Pfizer, Inc. had in its possession and produced the Undisclosed Swedish '822 Patent.

61. Upon information and belief, Applicants intentionally failed to disclose the Undisclosed Swedish '822 Patent to the examiner because it would have invalidated claims in the '185 Application.

62. By reason of the foregoing, Applicants breached their duty of candor and disclosure under 37 C.F.R. 1.56 by intentionally failing to disclose the Undisclosed Swedish '822 Patent to the examiner during the prosecution of the '185 Application with the intent to deceive the PTO and procure a patent. Applicants failed to disclose the Swedish '822 Patent despite their knowledge of this reference and its high degree of materiality. The '600 Patent is therefore rendered unenforceable by inequitable conduct.

B. Misrepresentation Of Unexpected Results Over Prior Art

Introduction

63. In a series of office actions, the patent examiner repeatedly rejected the '185 Application as obvious over prior art U.S. Patent No. 3,446,901 ("the '901 Patent") based on his findings that the '901 Patent "generically teaches the present compounds and specifically discloses the dimethylamino lower homolog" and that the "[s]election from within a genus is held to be within the skill of the worker in the art absent a show of unexpected properties."

64. In order to overcome the examiner's rejections for obviousness, and procure a patent, Applicants undertook to demonstrate to the PTO that the compounds claimed in the '185 Application demonstrated unexpected properties over the prior art. In their efforts to overcome the patent examiner's rejections for obviousness, however, Applicants breached their duty of candor and disclosure in dealing with the PTO by knowingly and willfully making material misrepresentations, misleading statements, and omissions during the prosecution of the '185 Application with the intent to deceive the PTO. Applicants misrepresented the expected

properties of the compounds disclosed in the '901 Patent; misrepresented the identity of the prior art compound that was closest in chemical structure to the claimed compounds; failed to disclose that one of the claimed compounds Applicants used to purportedly demonstrate unexpected properties had previously been disclosed in the prior art; and submitted a false and misleading declaration by an inventor, Lisbeth Nilvebrant, that misrepresented that tests established that certain claimed compounds were approximately six to seven times better than a prior art compound with respect to anticholinergic activity, all as alleged in further detail hereafter.

1. ***Expected Properties of Compounds Disclosed by '901 Patent***

65. First, Applicants knowingly, willfully and with the intent to deceive the PTO and procure a patent misrepresented the expected properties of the compounds disclosed in the '901 Patent in order to marginalize the importance of the '901 Patent to the claims of the '185 Application.

66. In order to overcome the patent examiner's rejections for obviousness, Applicants represented that the '901 Patent did not concern anticholinergic agents and therefore there would be no motivation to experiment with or modify the compounds disclosed in the '901 Patent in an attempt to invent, discover or synthesize a new compound with anticholinergic properties. Applicants specifically represented that "[s]ince the ['901 Patent] is not concerned with anticholinergic agents, the selection of substituents to arrive at the compounds of the present invention would merely be fortuitous without any reasonable degree of expectation that the properties achieved by the present invention would be obtained."

67. To the contrary, however, it was known in the art, and at least by inventor Nils A. Jönsson, that antidepressant compounds, such as those disclosed in the '901 Patent, often also have anticholinergic properties. Indeed, inventor Jönsson initially investigated such compounds

in an attempt to identify potential anticholinergic agents based on his understanding that anticholinergic activity was often a side effect of drugs used as antidepressants. Therefore, it would not have been "merely [] fortuitous" or unexpected that a compound disclosed in the '901 Patent would have anticholinergic properties.

68. Applicants' misrepresentations regarding the expected properties of the compounds disclosed in the '901 Patent were material because they contradict Applicants' assertion that the claimed compounds exhibit unexpected properties when compared to the prior art. Applicants, and particularly inventor Jönsson, knew or should have known that such information was material to the prosecution of the '185 Application.

69. By reason of the foregoing, Applicants, including inventor Jönsson, knowingly, willfully and with the intent to deceive the PTO and procure a patent made material misrepresentations concerning the expected properties of the compounds disclosed in the '901 Patent. As a result, the '600 Patent is rendered unenforceable by inequitable conduct.

2. *Closest Prior Art Compound*

70. Second, Applicants knowingly, willfully and with the intent to deceive the PTO and procure a patent misrepresented which prior art compound was closest in chemical structure to the compounds claimed in the '185 Application.

71. In their attempt to establish that the claimed invention exhibited unexpected properties when compared to the prior art, Applicants chose a "reference" prior art compound from the '901 Patent and compared it to compounds claimed in the '185 Application. The reference compound Applicants chose was N,N-dimethyl-3-(2-methoxy)-3-phenylpropylamine ("Jones Reference Compound"), which has two carbons on the nitrogen (the two carbons plus the nitrogen constitute an "amine group"). Applicants represented to the PTO that the Jones

Reference Compound was "considered to be the closest prior art as regards chemical structure." At the time Applicants chose the Jones Reference Compound with two carbons in the amine group, the broadest claim of the purported invention required a minimum of three carbons in the amine group (Applicants later amended the Application to require four carbons in the amine group).

72. Applicants knew, however, that the '901 Patent discloses at least two separate compounds that have three carbon amine groups: the '901 Patent specifically discloses N-ethyl-N-methyl-3,3-diphenylpropylamine (three carbon amines) and generally discloses N-methyl, N-ethyl-3-(methoxyphenyl)-3-phenylpropylamine (also three carbon amines). These three carbon amine compounds disclosed by the '901 Patent are closer in chemical structure to the compounds claimed in the '185 Application than the two carbon amine Jones Reference Compound chosen by Applicants. In fact, N-methyl, N-ethyl-3-(methoxyphenyl)-3-phenylpropylamine actually falls within the original claims of the '185 Application.

73. Thus, Applicants intentionally misrepresented that they were comparing the claimed compounds to the closest prior art compound, when in fact the three carbon amine compounds disclosed in the '901 Patent were closer prior art as regards chemical structure than the two carbon amine Jones Reference Compound. Applicants' misrepresentation regarding the closest prior art compound was material because the patentability of the claimed invention depended on Applicants' ability to demonstrate unexpected properties. This material information refutes Applicants' assertion that the claimed invention exhibits unexpected properties over the prior art. Applicants knew or should have known that such information was material to the prosecution of the '185 Application. As a result, the '600 Patent is rendered unenforceable by inequitable conduct.

3. ***"Compound (A)"***

74. Third, in their attempt to establish that the claimed invention exhibited unexpected properties when compared to the prior art, Applicants reported test results to the PTO purporting to compare two claimed compounds with the Jones Reference Compound, which Applicants represented was the closest prior art compound. Applicants represented that such test results demonstrated that the two claimed compounds – identified by Applicants as compound (A) and compound (B) – exhibited unexpected properties with respect to anticholinergic activity when compared to what they claimed was the closest prior art compound.

75. In making such representations, however, Applicants knowingly, intentionally and with the intent to deceive the PTO and procure a patent failed to disclose that compound (A)—N-methyl, N-isopropyl-3-(methoxyphenyl)-3-phenylpropylamine—had already been disclosed by the prior art '901 Patent and claimed by a related prior art patent also before the examiner, GB1,169,945 (the "British '945 Patent").

76. Therefore, Applicants' representation that compound (A) exhibited unexpected properties in comparison to the closest prior art compound was false and misleading because compound (A) itself was a compound that had already been disclosed and claimed in the prior art.

77. Applicants' false and misleading statements and material omissions regarding the identity of compound (A) were material because they contradict Applicants' representation that the claimed invention exhibited unexpected properties over the prior art. Applicants knew or should have known that such information was material to the prosecution of the '185 Application.

78. By reason of the foregoing, Applicants knowingly, willfully and with the intent to deceive the PTO and procure a patent failed to disclose to the patent examiner the material fact that claimed compound (A) had been disclosed and claimed in the prior art. As a result, the '600 Patent is rendered unenforceable by inequitable conduct.

4. *Nilvebrant Declaration*

79. Fourth, in order to overcome the patent examiner's final rejection, Applicants knowingly, willfully and with the intent to deceive the PTO and procure a patent submitted a false and misleading declaration from inventor Lisbeth Nilvebrant ("Nilvebrant Declaration") in an effort to demonstrate that the claimed invention exhibited unexpected properties over what Applicants claimed was the closest compound in the prior art.

80. The Nilvebrant Declaration represented that the reported results from "comparative tests" "establish that the compounds (A) and (B) that were tested are approximately six to seven times better than the compound according to Jones [the Jones Reference Compound], with respect to anticholinergic activity. . . ." This representation was false and misleading in a number of ways.

81. Applicants' representation that "comparative tests" were performed was false and misleading. In fact, the "tests" referred to in the Nilvebrant Declaration were comparisons of pharmacological data measuring the anticholinergic activity of different compounds from tests conducted years apart, by different laboratory technicians, and under different experimental conditions. As a result, the analytical results reported in the Nilvebrant Declaration were not "comparative tests" as that term was understood in the art and by at least inventor Nilvebrant.

82. Applicants' representation that the test results reported in the Nilvebrant Declaration established that compounds (A) and (B) were approximately six to seven times

better than the Jones Reference Compound with respect to anticholinergic activity was also false and misleading, because the data referred to in the Nilvebrant Declaration was derived from pharmacological testing that lacked the necessary precision, accuracy, and reproducibility to be scientifically reliable. The tests that Applicants conducted provided insufficient and inadequate data to make scientifically reliable representations to the PTO purporting to compare compounds (A) and (B) with the Jones Reference Compound. Among other things, the data concerning compound (A) was derived from only one test of compound (A) and the data concerning compound (B) was derived from only two tests of compound (B). As Applicants, including specifically inventor Nilvebrant, well knew, a minimum of three tests with respect to each compound was necessary in order for the results to be scientifically reliable.

83. Applicants, including inventor Nilvebrant, further misled the patent examiner by indicating that there was a statistically significant difference in anticholinergic activity between compounds (A) and (B) and the Jones Reference Compound. Applicants' suggestion was false and misleading because they never performed any statistical analysis on the test results they had with respect to compound (A), compound (B) and the Jones Reference Compound.

84. Applicants, and particularly inventor Nilvebrant, had knowledge of the pharmacological data underlying the test results reported in the Nilvebrant Declaration and therefore knew that the representations made in the Nilvebrant Declaration were scientifically unreliable, false and misleading.

85. Applicants' misrepresentations in the Nilvebrant Declaration are material because they contradict Applicants' assertion that the claimed invention exhibited unexpected properties over the prior art. The misrepresentations in the Nilvebrant Declaration are also material because the patent examiner conditioned his allowance of the claims on the submission of the

Nilvebrant Declaration. Only by submitting the Nilvebrant Declaration were Applicants able to overcome the patent examiner's rejections and obtain the '600 Patent. Applicants, including inventor Nilvebrant, knew or should have known such information was material to the prosecution of the '185 Application.

86. By reason of the foregoing, Applicants, including inventor Nilvebrant, knowingly, willfully and with the intent to deceive the PTO and procure a patent submitted the false and misleading Nilvebrant Declaration. As a result, the '600 Patent is rendered unenforceable by inequitable conduct.

TEVA'S COUNTERCLAIMS

For its Counterclaims, Teva alleges as follows:

THE PARTIES

1. Teva Pharmaceuticals USA, Inc. ("Teva") is a Delaware corporation with a principal place of business in North Wales, Pennsylvania.

2. Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 235 East 42nd Street, New York, NY.

3. Pharmacia & Upjohn Company LLC is a corporation organized and existing under the laws of the State of Delaware having a place of business at 7000 Portage Road, Kalamazoo, MI. Pfizer Inc. is ultimate parent of Pharmacia & Upjohn Company LLC.

4. Pfizer Health AB is a company organized and existing under the laws of Sweden, having a place of business at SE-112 87, Stockholm, Sweden. Pfizer, Inc. is the ultimate parent of Pfizer Health AB. Pfizer Inc., Pharmaceia & Upjohn Company LLC, and Pfizer Health AB are hereinafter collectively referred to as "Pfizer."

JURISDICTION AND VENUE

5. These Counterclaims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*.

6. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, 2202.

7. This Court has personal jurisdiction over Pfizer at least for the reason that Pfizer has submitted to the jurisdiction of this Court by virtue of filing its Complaint.

8. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE CONTROVERSY

9. In its Complaint, Pfizer asserts ownership of U.S. Patent No. 5,382,600 (the "'600 Patent"), U.S. Patent No. 6,630,162 (the "'162 Patent") and U.S. Patent No. 6,770,295 (the "'295 Patent") and alleges infringement of the '600, '162 and '295 Patents by Teva.

10. Pursuant to the Federal Food, Drug, and Cosmetics Act, 21 U.S.C. §§ 355(j), Teva's ANDA No. 79-141 contains a certification by Teva stating that in its opinion, the '600, '162 and '295 Patents are invalid, unenforceable or not infringed. Notice of that certification was sent to Pfizer.

11. Teva's importation, sale or offer for sale of Teva's proposed generic tolterodine tartrate extended release capsules, in 2 and 4 mg dosages, that are the subject of ANDA 79-141, and the administration of those products within the United States will not infringe any valid or enforceable claim of the '600, '162 and '295 Patents.

12. Upon information and belief, Pfizer's charge of infringement, after being advised by Teva as to why there is no basis for such charge, and other conduct yet to be discovered, renders this case exceptional within the meaning of 35 U.S.C. § 285.

COUNTERCLAIM 1

Declaratory Judgment of Invalidity of the '600 Patent

13. Teva realleges paragraphs 1-12 above as fully set forth herein.

14. An actual controversy exists between Teva and Pfizer concerning the validity of the '600 Patent, which requires a declaration of rights by this Court.

15. All claims of the '600 Patent are invalid for failing to comply with the requirements of the Patent Laws of the United States, 35 U.S.C. §§ 101, 102, 103 and 112.

COUNTERCLAIM 2

Declaratory Judgment of Invalidity of the '162 Patent

16. Teva realleges paragraphs 1-12 above as fully set forth herein.

17. An actual controversy exists between Teva and Pfizer concerning the validity of the '162 Patent, which requires a declaration of rights by this Court.

18. All claims of the '162 Patent are invalid for failing to comply with the requirements of the Patent Laws of the United States, 35 U.S.C. §§ 101, 102, 103 and 112.

COUNTERCLAIM 3

Declaratory Judgment of Invalidity of the '295 Patent

19. Teva realleges paragraphs 1-12 above as fully set forth herein.

20. An actual controversy exists between Teva and Pfizer concerning the validity of the '295 Patent, which requires a declaration of rights by this Court.

21. All claims of the '295 Patent are invalid for failing to comply with the requirements of the Patent Laws of the United States, 35 U.S.C. §§ 101, 102, 103 and 112.

COUNTERCLAIM 4

Declaratory Judgment of Non-Infringement of the '162 Patent

22. Teva realleges paragraphs 1-12 above as fully set forth herein.

23. An actual controversy exists between Teva and Pfizer concerning the infringement of the '162 Patent, which requires a declaration of rights by this Court.

24. The manufacture, use, offer for sale, sale or importation of the Teva's tolterodine tartrate extended release capsules, in 2 and 4 mg dosages, that are the subject of ANDA 79-141 does not and will not infringe any valid claim of the '162 Patent.

COUNTERCLAIM 5

Declaratory Judgment of Non-Infringement of the '295 Patent

25. Teva realleges paragraphs 1-12 above as fully set forth herein.

26. An actual controversy exists between Teva and Pfizer concerning the infringement of the '295 Patent, which requires a declaration of rights by this Court.

27. The manufacture, use, offer for sale, sale or importation of the Teva's tolterodine tartrate extended release capsules, in 2 and 4 mg dosages, that are the subject of ANDA 79-141 does not and will not infringe any valid claim of the '295 Patent.

COUNTERCLAIM 6

Declaratory Judgment of Unenforceability of the '600 Patent

Introduction

28. Teva realleges paragraphs 1-12 above as fully set forth herein.

29. This matter concerns, *inter alia*, United States Patent No. 5,382,600 (the "'600 Patent") entitled "3,3-Diphenylpropylamines and Pharmaceutical Compositions Thereof" issued by the United States Patent and Trademark Office ("PTO") on January 17, 1995.

30. The named inventors, their attorneys and others who had substantive involvement in the prosecution of the '600 Patent owed a duty of candor and disclosure to the PTO under 37 C.F.R. § 1.56 with respect to and during the pendency of the prosecution of the '600 Patent. Individuals who had such a duty of candor and disclosure include inventors Nils A. Jönsson, Bengt A. Sparf, Lembit Mikiver, Pinchas Moses, Lisbeth Nilvebrant, and Gunilla Glas; originating/introducing Swedish patent agents or attorneys Per Arne Kummelsten and Bjorn Widen; and certain others, including Rolf Johansson and Per-Olof Andersson (hereinafter, collectively, "Applicants").

31. Applicants' duties included an obligation to disclose information material to the prosecution and patentability of the '600 Patent to the PTO, as required by the Manual of Patent Examiner Procedure ("M.P.E.P.") in effect during prosecution of the '600 Patent, which stated the following:

> Applicants and other individuals, as set forth in 37 C.F.R. 1.56, have a duty to bring to the attention of the Office any material prior art or other information cited or brought to their attention in any related foreign application. The inference that such prior art or other information is material is especially strong where it is the only prior art cited or where it has been used in rejecting the same or similar claims in the foreign application.

M.P.E.P. § 2001.06(a).

32. The '600 Patent is unenforceable because Applicants breached their duty of candor and disclosure by intentionally failing to disclose German Patent No. 1216318 (the "Undisclosed German '318 Patent") and Swedish Patent No. 300 822 (the "Undisclosed Swedish

'822 Patent") to the PTO during the prosecution of the '600 Patent despite their knowledge of these references and their high degree of materiality. Applicants failed to disclose these material references with the intent to deceive the PTO, and the '600 Patent is therefore rendered unenforceable by inequitable conduct.

33. The '600 Patent is also unenforceable because Applicants breached their duty of candor and disclosure by intentionally making material misrepresentations and misleading statements to the PTO in order to procure a patent. Applicants made these material misrepresentations and misleading statements with the intent to deceive the PTO, and the '600 Patent is therefore rendered unenforceable by inequitable conduct.

Background - Prosecution of the '600 Patent and Related Applications

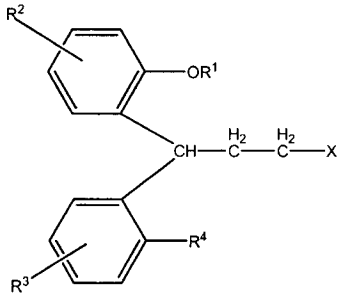
34. The '600 Patent issued from U.S. Patent Application Ser. No. 810,185 (the "'185 Application") entitled "3,3-Diphenylpropylamines and Pharmaceutical Compositions Thereof." The '185 Application was filed on December 19, 1991. At the time of filing, Kabi Vitrum AB, Stockholm, Sweden, was the designated assignee. The assignment was later changed to Pharmacia Aktiebiolag, Uppsala, Sweden, as appears on the face of the '600 Patent.

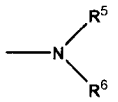
35. The '185 Application derived priority from an International Patent Cooperation Treaty ("PCT") Application No. 8900016 (the "'016 Priority Application"). The International Publication Number for the '016 Priority Application is WO8906644.

36. The '016 Priority Application was prosecuted by Kummelsten, Per Arne *et. al.*, attorneys from the Swedish law firm, Uppsala Patentbyra. Bjorn Widen was an attorney at Uppsala Patentbyra, who was specifically named as a prosecuting attorney on national applications which resulted from the '016 Priority Application. Upon information and belief, Bjorn Widen participated in the prosecution of the '016 Priority Application.

37. The '185 Application and the issued '600 Patent each identify Nils A. Jonsson, Bengt A. Sparf, Lembit Mikiver, Pinchas Moses, Lisbeth Nilvebrant and Gunilla Glas as inventors.

38. The '185 Application described and claimed diphenylpropylamines of formula I:



> wherein R^1 signifies hydrogen or methyl, R^2, R^3 and R^4 independently signify hydrogen, methyl, methoxy, hydroxy, carbamoyl, sulphamoyl or halogen, and X represents a tertiary amino group of formula II
>
> 
>
>
> wherein each of R^5 and R^6 independently signifies C_{1-6} alkyl, which may be joined to form a ring with the amine nitrogen and each of which may carry a hydroxy substituent, or adamantyl, and wherein R^5 and R^6 together contain at least three carbon atoms, preferably at least 4 carbon atoms, their salts with physiologically acceptable acids and, when the compounds can be in the form of optical isomers, the racemic mixture and the individual enantiomers.

A. Failure To Disclose Certain Prior Art

1. Failure to Disclose German Patent No. 1216318

39. During prosecution of the '185 Application, the examiner rejected claims 1 to 4, 6 and 9 to 15 "under 35 U.S.C. § 103 as obvious over the German, British and U.S. patents and the Chemical Abstracts article cited in the corresponding PCT application [the '016 Priority Application]." The '016 Priority Application cited two British patents (GB 1169944 and GB 1169945), one U.S. patent (3,446,901), and Chemical Abstract, Vol. 97 (1982) 120105N. It did

not cite any German patents. The examiner requested copies of "the German [and] British … patents" from the Applicants for his review.

40. When the examiner made the request and otherwise during the prosecution of the '600 Patent, Applicants were aware of a highly material German patent, German Patent No. 1216318 ("Undisclosed German '318 Patent"). Applicants' knowledge is evidenced by the fact that the face of the Danish Patent No. 111894 ("Danish '894 Patent"), which was provided to the examiner by Applicants, cites to the application for the Undisclosed German '318 Patent for priority, a fact which was highlighted by the examiner of the '185 Application's request for a German reference.

41. Applicants' knowledge of the Undisclosed German '318 Patent is further evidenced by the fact that, in a related application, the Undisclosed German patent was identified to several of Applicants as "document of particular relevance," and was cited as invalidating prior art.

42. During the prosecution of the '185 Application, Swedish Application No. 92003318 (the "Swedish Metabolite Application") was filed on November 6, 1992. The specification and claims of the Swedish Metabolite Application were submitted as a PCT application, No. SE93/00927, on November 5, 1993 (the "PCT Metabolite Application").

43. The specification of the PCT Metabolite application specifically references the subject matter of the '185 Application, and the compounds claimed in the PCT Metabolite Application only differ from those claimed in the '185 Application (as described in Formula I, paragraph 29 above) by one substituent group – the R^2 group in the PCT Metabolite Application is specified as a methanol group.

44. Three of the inventors identified in the '185 Application and the '600 Patent, Bengt A. Sparf, Pinchas Moses, and Lisbeth Nilvebrant, are also identified as inventors on the PCT Metabolite Application. In addition, the PCT Metabolite Application was prosecuted by Bjorn Widen, an attorney at Uppsala Patentbyra. Thus, inventors Bengt A. Sparf, Pinchas Moses and Lisbeth Nilvebrant, and attorney Bjorn Widen participated in the prosecution of both the PCT Metabolite Application and the '185 Application (which issued as the '600 Patent).

45. The examiner of the PCT Metabolite Application designated the Undisclosed German '318 Patent as type "X" in an International Search Report ("ISR") sent to inventors Sparf, Moses and Nilvebrant and attorney Widen on February 7, 1994. A type "X" reference is defined in the ISR as a "document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when taken alone."

46. The examiner of the PCT Metabolite Application also designated WO8906644 (the formal publication of the '016 Priority Application, which is the predecessor of the '185 Application) as a type "X" reference. The examiner determined that the predecessor of the '185 Application was invalidating prior art and on that basis refused the PCT Metabolite Application.

47. A reasonable PTO examiner would have considered the Undisclosed German '318 Patent to be highly material to the patentability of the '185 Application for at least the following reasons: (1) the Undisclosed German '318 Patent was designated as particularly relevant prior art regarding the PCT Metabolite Application, which specifically references the subject matter of the '185 application and, with the exception of one substituent group, claims compounds identical to those claimed in the '185 Application, (2) the teachings of Undisclosed German '318 Patent are inconsistent with and could not have been distinguished by arguments made by Applicants, and (3) the Undisclosed German '318 Patent discloses compounds that are

claimed in the '185 Application and the '600 Patent, and therefore anticipates the claims of the '600 Patent and/or renders the claims of the '600 Patent obvious.

48. Applicants also had knowledge of the materiality of the Undisclosed German '318 Patent while prosecuting the '185 Application. Applicants' knowledge is evidenced by (1) the determination in the ISR that the Undisclosed German '318 Patent was of type "X", and therefore invalidated the claims of the Swedish Metabolite Application; (2) the fact that the Undisclosed German '318 Patent described a class of compounds that contained an alkoxy substituent, which description is inconsistent with and avoids Applicants' argument for distinguishing the claimed compounds of the '185 Application from the related Danish '894 Patent; and (3) the fact that the Undisclosed German '318 Patent described a class of compounds identical to a subset of the claims of the '185 Application and the '600 Patent, and therefore anticipated those claims.

49. Despite the PTO examiner's request for the German patent and despite their knowledge of such patent and its high degree of materiality, Applicants did not provide a copy nor did they disclose to the PTO the Undisclosed German Patent. Applicants intentionally failed to disclose the Undisclosed German '318 Patent to the PTO because it would have invalidated claims in the '185 Application (which issued as the '600 Patent).

50. Instead, in their response to the examiner's request for the German patent, Applicants cited and produced to the examiner Danish Patent No. 111894 (the "Danish '894 Patent"). The Danish '894 Patent, on its face, claimed priority to German Patent Application No. K48245, filed in November, 1962, which application issued as the Undisclosed German '318 Patent.

51. In further response to the examiner's rejection, Applicants distinguished the Danish '894 Patent by arguing that it did not teach placing an hydroxy or alkoxy substituent in the ortho position of the phenyl rings. That argument would not have distinguished the Undisclosed German '318 Patent, however, which discloses an alkoxy substituent in the ortho position of the phenyl rings.

52. As a result, Applicants breached their duty of candor under 37 C.F.R. § 1.56 by intentionally failing to disclose the Undisclosed German '318 Patent to the examiner during the prosecution of the '185 Application with the intent to deceive the PTO and procure a patent. Applicants failed to disclose the Undisclosed German '318 despite their knowledge of the reference and its high degree of materiality. Therefore, the '600 Patent is rendered unenforceable by inequitable conduct.

2. ***Failure to Disclose Material Swedish Patent No. 300 822***

53. Applicants also intentionally failed to disclose Swedish Patent No. 300 822 (the "Undisclosed Swedish '822 Patent") to the examiner during the prosecution of the '600 Patent despite their knowledge of this reference and its high degree of materiality. The Undisclosed Swedish '822 Patent, which claims priority to the Undisclosed German '318 Patent, is related to and contains similar disclosures to the Danish '894 Patent. Like the Undisclosed German '318 Patent but unlike the Danish '894 Patent, the Undisclosed Swedish '822 Patent describes substituted diphenylpropylamines with an alkoxy substituent in the phenyl rings.

54. In response to the examiner's rejection for obviousness, Applicants distinguished the Danish '894 Patent by arguing that it did not teach placement of an hydroxy or alkoxy substituent in the ortho position of the phenyl rings. That argument would not have

distinguished the Undisclosed Swedish '822 Patent, however, which discloses an alkoxy substituent in the ortho position of the phenyl rings.

55. A reasonable examiner would have considered the Undisclosed Swedish '822 Patent material to the patentability of the '185 Application because, in addition to the reasons stated as to the Undisclosed German '318 Patent in paragraphs 37 and 38 above, the Undisclosed Swedish '822 Patent describes compounds that fall within the claims of the '600 Patent, and thereby renders the claims of the '600 Patent anticipated and/or obvious.

56. Upon information and belief, Applicants were aware of the Undisclosed Swedish '822 Patent and its materiality during the prosecution of the '185 Application, as evidenced by the following: (1) Applicants disclosed the Danish '894 Patent, which is related to the Undisclosed Swedish '822 Patent and claims priority to the same parent; (2) the Undisclosed Swedish '822 Patent is issued by the Swedish Patent Office in the Swedish language and covers the class of compounds for which Applicants sought to obtain a patent; (3) Applicants are Swedish nationals, developed the compounds claimed in the '185 Application in Sweden, and filed a priority application to the '185 Application with the Swedish Patent Office; and (4) Plaintiff Pfizer, Inc. had in its possession and produced the Undisclosed Swedish '822 Patent.

57. Upon information and belief, Applicants intentionally failed to disclose the Undisclosed Swedish '822 Patent to the examiner because it would have invalidated claims in the '185 Application.

58. By reason of the foregoing, Applicants breached their duty of candor and disclosure under 37 C.F.R. 1.56 by intentionally failing to disclose the Undisclosed Swedish '822 Patent to the examiner during the prosecution of the '185 Application with the intent to deceive the PTO and procure a patent. Applicants failed to disclose the Swedish '822 Patent

despite their knowledge of this reference and its high degree of materiality. The '600 Patent is therefore rendered unenforceable by inequitable conduct.

B. Misrepresentation Of Unexpected Results Over Prior Art

Introduction

59. In a series of office actions, the patent examiner repeatedly rejected the '185 Application as obvious over prior art U.S. Patent No. 3,446,901 ("the '901 Patent") based on his findings that the '901 Patent "generically teaches the present compounds and specifically discloses the dimethylamino lower homolog" and that the "[s]election from within a genus is held to be within the skill of the worker in the art absent a show of unexpected properties."

60. In order to overcome the examiner's rejections for obviousness, and procure a patent, Applicants undertook to demonstrate to the PTO that the compounds claimed in the '185 Application demonstrated unexpected properties over the prior art. In their efforts to overcome the patent examiner's rejections for obviousness, however, Applicants breached their duty of candor and disclosure in dealing with the PTO by knowingly and willfully making material misrepresentations, misleading statements, and omissions during the prosecution of the '185 Application with the intent to deceive the PTO. Applicants misrepresented the expected properties of the compounds disclosed in the '901 Patent; misrepresented the identity of the prior art compound that was closest in chemical structure to the claimed compounds; failed to disclose that one of the claimed compounds Applicants used to purportedly demonstrate unexpected properties had previously been disclosed in the prior art; and submitted a false and misleading declaration by an inventor, Lisbeth Nilvebrant, that misrepresented that tests established that certain claimed compounds were approximately six to seven times better than a prior art compound with respect to anticholinergic activity, all as alleged in further detail hereafter.

1. ***Expected Properties of Compounds Disclosed by '901 Patent***

61. First, Applicants knowingly, willfully and with the intent to deceive the PTO and procure a patent misrepresented the expected properties of the compounds disclosed in the '901 Patent in order to marginalize the importance of the '901 Patent to the claims of the '185 Application.

62. In order to overcome the patent examiner's rejections for obviousness, Applicants represented that the '901 Patent did not concern anticholinergic agents and therefore there would be no motivation to experiment with or modify the compounds disclosed in the '901 Patent in an attempt to invent, discover or synthesize a new compound with anticholinergic properties. Applicants specifically represented that "[s]ince the ['901 Patent] is not concerned with anticholinergic agents, the selection of substituents to arrive at the compounds of the present invention would merely be fortuitous without any reasonable degree of expectation that the properties achieved by the present invention would be obtained."

63. To the contrary, however, it was known in the art, and at least by inventor Nils A. Jönsson, that antidepressant compounds, such as those disclosed in the '901 Patent, often also have anticholinergic properties. Indeed, inventor Jönsson initially investigated such compounds in an attempt to identify potential anticholinergic agents based on his understanding that anticholinergic activity was often a side effect of drugs used as antidepressants. Therefore, it would not have been "merely [] fortuitous" or unexpected that a compound disclosed in the '901 Patent would have anticholinergic properties.

64. Applicants' misrepresentations regarding the expected properties of the compounds disclosed in the '901 Patent were material because they contradict Applicants' assertion that the claimed compounds exhibit unexpected properties when compared to the prior

art. Applicants, and particularly inventor Jönsson, knew or should have known that such information was material to the prosecution of the '185 Application.

65. By reason of the foregoing, Applicants, including inventor Jönsson, knowingly, willfully and with the intent to deceive the PTO and procure a patent made material misrepresentations concerning the expected properties of the compounds disclosed in the '901 Patent. As a result, the '600 Patent is rendered unenforceable by inequitable conduct.

2. *Closest Prior Art Compound*

66. Second, Applicants knowingly, willfully and with the intent to deceive the PTO and procure a patent misrepresented which prior art compound was closest in chemical structure to the compounds claimed in the '185 Application.

67. In their attempt to establish that the claimed invention exhibited unexpected properties when compared to the prior art, Applicants chose a "reference" prior art compound from the '901 Patent and compared it to compounds claimed in the '185 Application. The reference compound Applicants chose was N,N-dimethyl-3-(2-methoxy)-3-phenylpropylamine ("Jones Reference Compound"), which has two carbons on the nitrogen (the two carbons plus the nitrogen constitute an "amine group"). Applicants represented to the PTO that the Jones Reference Compound was "considered to be the closest prior art as regards chemical structure." At the time Applicants chose the Jones Reference Compound with two carbons in the amine group, the broadest claim of the purported invention required a minimum of three carbons in the amine group (Applicants later amended the Application to require four carbons in the amine group).

68. Applicants knew, however, that the '901 Patent discloses at least two separate compounds that have three carbon amine groups: the '901 Patent specifically discloses N-ethyl-

N-methyl-3,3-diphenylpropylamine (three carbon amines) and generally discloses N-methyl, N-ethyl-3-(methoxyphenyl)-3-phenylpropylamine (also three carbon amines). These three carbon amine compounds disclosed by the '901 Patent are closer in chemical structure to the compounds claimed in the '185 Application than the two carbon amine Jones Reference Compound chosen by Applicants. In fact, N-methyl, N-ethyl-3-(methoxyphenyl)-3-phenylpropylamine actually falls within the original claims of the '185 Application.

69. Thus, Applicants intentionally misrepresented that they were comparing the claimed compounds to the closest prior art compound, when in fact the three carbon amine compounds disclosed in the '901 Patent were closer prior art as regards chemical structure than the two carbon amine Jones Reference Compound. Applicants' misrepresentation regarding the closest prior art compound was material because the patentability of the claimed invention depended on Applicants' ability to demonstrate unexpected properties. This material information refutes Applicants' assertion that the claimed invention exhibits unexpected properties over the prior art. Applicants knew or should have known that such information was material to the prosecution of the '185 Application. As a result, the '600 Patent is rendered unenforceable by inequitable conduct.

3. *"Compound (A)"*

70. Third, in their attempt to establish that the claimed invention exhibited unexpected properties when compared to the prior art, Applicants reported test results to the PTO purporting to compare two claimed compounds with the Jones Reference Compound, which Applicants represented was the closest prior art compound. Applicants represented that such test results demonstrated that the two claimed compounds – identified by Applicants as compound

(A) and compound (B) – exhibited unexpected properties with respect to anticholinergic activity when compared to what they claimed was the closest prior art compound.

71. In making such representations, however, Applicants knowingly, intentionally and with the intent to deceive the PTO and procure a patent failed to disclose that compound (A)—N-methyl, N-isopropyl-3-(methoxyphenyl)-3-phenylpropylamine—had already been disclosed by the prior art '901 Patent and claimed by a related prior art patent also before the examiner, GB1,169,945 (the "British '945 Patent").

72. Therefore, Applicants' representation that compound (A) exhibited unexpected properties in comparison to the closest prior art compound was false and misleading because compound (A) itself was a compound that had already been disclosed and claimed in the prior art.

73. Applicants' false and misleading statements and material omissions regarding the identity of compound (A) were material because they contradict Applicants' representation that the claimed invention exhibited unexpected properties over the prior art. Applicants knew or should have known that such information was material to the prosecution of the '185 Application.

74. By reason of the foregoing, Applicants knowingly, willfully and with the intent to deceive the PTO and procure a patent failed to disclose to the patent examiner the material fact that claimed compound (A) had been disclosed and claimed in the prior art. As a result, the '600 Patent is rendered unenforceable by inequitable conduct.

4. *Nilvebrant Declaration*

75. Fourth, in order to overcome the patent examiner's final rejection, Applicants knowingly, willfully and with the intent to deceive the PTO and procure a patent submitted a

false and misleading declaration from inventor Lisbeth Nilvebrant ("Nilvebrant Declaration") in an effort to demonstrate that the claimed invention exhibited unexpected properties over what Applicants claimed was the closest compound in the prior art.

76. The Nilvebrant Declaration represented that the reported results from "comparative tests" "establish that the compounds (A) and (B) that were tested are approximately six to seven times better than the compound according to Jones [the Jones Reference Compound], with respect to anticholinergic activity. . . ." This representation was false and misleading in a number of ways.

77. Applicants' representation that "comparative tests" were performed was false and misleading. In fact, the "tests" referred to in the Nilvebrant Declaration were comparisons of pharmacological data measuring the anticholinergic activity of different compounds from tests conducted years apart, by different laboratory technicians, and under different experimental conditions. As a result, the analytical results reported in the Nilvebrant Declaration were not "comparative tests" as that term was understood in the art and by at least inventor Nilvebrant.

78. Applicants' representation that the test results reported in the Nilvebrant Declaration established that compounds (A) and (B) were approximately six to seven times better than the Jones Reference Compound with respect to anticholinergic activity was also false and misleading, because the data referred to in the Nilvebrant Declaration was derived from pharmacological testing that lacked the necessary precision, accuracy, and reproducibility to be scientifically reliable. The tests that Applicants conducted provided insufficient and inadequate data to make scientifically reliable representations to the PTO purporting to compare compounds (A) and (B) with the Jones Reference Compound. Among other things, the data concerning compound (A) was derived from only one test of compound (A) and the data concerning

compound (B) was derived from only two tests of compound (B). As Applicants, including specifically inventor Nilvebrant, well knew, a minimum of three tests with respect to each compound was necessary in order for the results to be scientifically reliable.

79. Applicants, including inventor Nilvebrant, further misled the patent examiner by indicating that there was a statistically significant difference in anticholinergic activity between compounds (A) and (B) and the Jones Reference Compound. Applicants' suggestion was false and misleading because they never performed any statistical analysis on the test results they had with respect to compound (A), compound (B) and the Jones Reference Compound.

80. Applicants, and particularly inventor Nilvebrant, had knowledge of the pharmacological data underlying the test results reported in the Nilvebrant Declaration and therefore knew that the representations made in the Nilvebrant Declaration were scientifically unreliable, false and misleading.

28. Applicants' misrepresentations in the Nilvebrant Declaration are material because they contradict Applicants' assertion that the claimed invention exhibited unexpected properties over the prior art. The misrepresentations in the Nilvebrant Declaration are also material because the patent examiner conditioned his allowance of the claims on the submission of the Nilvebrant Declaration. Only by submitting the Nilvebrant Declaration were Applicants able to overcome the patent examiner's rejections and obtain the '600 Patent. Applicants, including inventor Nilvebrant, knew or should have known such information was material to the prosecution of the '185 Application.

81. By reason of the foregoing, Applicants, including inventor Nilvebrant, knowingly, willfully and with the intent to deceive the PTO and procure a patent submitted the false and

misleading Nilvebrant Declaration. As a result, the '600 Patent is rendered unenforceable by inequitable conduct.

PRAYER FOR RELIEF

Wherefore, Teva prays that this Court:

A. Enter judgment that Teva's Tolterodine ER Product does not infringe any valid or enforceable claim of U.S. Patent No. 5,382,600;

B. Enter judgment that Teva's Tolterodine ER Product does not infringe any valid or enforceable claim of U.S. Patent No. 6,630,162;

C. Enter judgment that Teva's Tolterodine ER Product does not infringe any valid or enforceable claim of U.S. Patent No. 6,770,295;

D. Enter declaratory judgment that U.S. Patent No. 5,382,600 is invalid for obviousness;

E. Enter declaratory judgment that U.S. Patent No. 6,630,162 is invalid;

F. Enter declaratory judgment that U.S. Patent No. 6,770,295 is invalid;

G. Enter declaratory judgment that U.S. Patent No. 5,382,600 is unenforceable for inequitable conduct;

H. Enter an order dismissing Pfizer's Complaint, with prejudice, and denying the relief requested in the Complaint;

I. Declare the case exceptional and award Teva reasonable attorneys' fees and costs; and

J. Grant such other and further relief as the Court deems proper and just.

JURY TRIAL CLAIM

TEVA CLAIMS TRIAL BY JURY AS TO ALL CLAIMS THAT MAY BE TRIED TO A JURY.

Dated: January 3, 2008

Respectfully submitted,

GOODWIN PROCTER LLP

/s/ David M. Hashmall
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CERTIFICATE OF SERVICE

I, David M. Hashmall hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on January 3, 2006.

/s/ David M. Hashmall